UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

85775

7590

08/16/2010

Locke Lord Bissell & Liddell LLP Attn: IP Docketing Three World Financial Center New York, NY 10281-2101 EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 08/16/2010

	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
Ī	10/599,479	12/19/2006	Masayoshi Shichiri	1004331.037US	9587

TITLE OF INVENTION: CARDIOINHIBITORY/ ANTIHYPERTENSIVE NOVEL ENDOGENOUS PHYSIOLOGICALLY ACTIVE PEPTIDE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	11/16/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where m

appropriate. All further indicated unless correct maintenance fee notifica	correspondence including debelow or directed off tions.	ng the Patent, advance onerwise in Block 1, by (orders and notification of a) specifying a new corre	maintenance fees espondence address	will be ; and/o	mailed to the current r (b) indicating a sepa	correspondence address as rate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) 85775 7590 08/16/2010 Locke Lord Bissell & Liddell LLP Attn: IP Docketing Three World Financial Center				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, mus have its own certificate of mailing or transmission.			
						· ·	miccion
				Certificate of Mailing or Transmission I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.			
New York, NY	10281-2101						(Depositor's name)
							(Signature)
			L				(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTO	R	ATTC	RNEY DOCKET NO.	CONFIRMATION NO.
10/599,479	12/19/2006	•	Masayoshi Shichiri	1004331.037U		1004331.037US	9587
TITLE OF INVENTION	: CARDIOINHIBITOR	Y/ ANTIHYPERTENSIV	E NOVEL ENDOGENO	US PHYSIOLOGIC	CALLY	ACTIVE PEPTIDE	
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSU	JE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0		\$1810	11/16/2010
EXAM	IINER	ART UNIT	CLASS-SUBCLASS				
KAM, Cl	HIH MIN	1656	514-002000	_			
 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). □ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. □ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer 			2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.				
PLEASE NOTE: Un	ND RESIDENCE DATA less an assignee is ident th in 37 CFR 3.11. Comp	ified below, no assignee	THE PATENT (print or t	ype) patent. If an assign assignment.			ocument has been filed for
Please check the appropr	riate assignee category or	categories (will not be p	rinted on the patent):	Individual 🗖 C	orporat	ion or other private gro	oup entity Government
4a. The following fee(s) are submitted: ☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies 5. Change in Entity Status (from status indicated above)			 . Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) □ A check is enclosed. □ Payment by credit card. Form PTO-2038 is attached. □ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form). 				
_ ~ .	i tus (from status indicate is SMALL ENTITY stati	*	☐ b. Applicant is no lo	nger claiming SMA	LL EN	TITY status. See 37 CF	FR 1.27(g)(2).
NOTE: The Issue Fee an	d Publication Fee (if rea		ed from anyone other than				e assignee or other party in
				Date			
Typed or printed name				Registration No.			
This collection of inform	nation is required by 37 (FR 1 311. The informati	on is required to obtain or	retain a benefit by	the pub	lic which is to file (and	by the USPTO to process)
an application. Confiden submitting the complete this form and/or suggest Box 1450, Alexandria, V Alexandria, Virginia 223	d application form to the ions for reducing this bu //irginia 22313-1450. DC 313-1450.	U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to th ONOT SEND FEES OR	y depending upon the induction of the chief Information Office COMPLETED FORMS	sumated to take 12 ividual case. Any c cer, U.S. Patent and TO THIS ADDRES	ommen Trader S. SEN	s to complete, including ts on the amount of tir mark Office, U.S. Depa D TO: Commissioner to	g gathering, preparing, and ne you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450,

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

OMB 0651-0033

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,479 12/19/2006		Masayoshi Shichiri	1004331.037US (4439-4047)	9587
85775 75	590 08/16/2010		EXAM	INER
Locke Lord Bissell & Liddell LLP			KAM, CI	HIH MIN
Attn: IP Docketing			ART UNIT	PAPER NUMBER
Three World Financial Center New York, NY 10281-2101			1656 DATE MAILED: 08/16/201	0

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 380 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 380 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	10/599,479	SHICHIRI, MASAYOSHI	
Notice of Allowability	Examiner	Art Unit	
	CHIH-MIN KAM	1656	
The MAILING DATE of this communication app All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85 NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT F of the Office or upon petition by the applicant. See 37 CFR 1.31	S (OR REMAINS) CLOSED (5) or other appropriate comm RIGHTS. This application is	n this application. If not included unication will be mailed in due course. THIS	
1. This communication is responsive to 8/3/10.			
2. ☑ The allowed claim(s) is/are <u>1,5 and 12-14</u> .			
3. Acknowledgment is made of a claim for foreign priority to a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 3. Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)). * Certified copies not received: Applicant has THREE MONTHS FROM THE "MAILING DATE noted below. Failure to timely comply will result in ABANDON THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submined in the submined part of the submined	ve been received. ve been received in Application ocuments have been received. " of this communication to fil MENT of this application. mitted. Note the attached EX ves reason(s) why the oath of the submitted. rson's Patent Drawing Review. r's Amendment / Comment of the header according to 37 C osit of BIOLOGICAL MAT	on No In add in this national stage application from the set a reply complying with the requirements. AMINER'S AMENDMENT or NOTICE OF or declaration is deficient. W (PTO-948) attached In the Office action of the drawings in the front (not the back) of FR 1.121(d). ERIAL must be submitted. Note the	
Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material //Chih-Min Kam/ Primary Examiner, Art Unit 1656	6. ☐ Interview S Paper No 7. ☑ Examiner's	nformal Patent Application Summary (PTO-413), /Mail Date s Amendment/Comment s Statement of Reasons for Allowance	
	1		

Application/Control Number: 10/599,479 Page 2

Art Unit: 1656

DETAILED ACTION

Status of the Claims

1. Claims 1, 5 and 10-15 are pending.

Applicants' amendment filed August 3, 2010 is acknowledged. Applicants' response has been fully considered. Claim 1 has been amended. Claims 10-11 and 15 are non-elected inventions and are withdrawn from consideration. Therefore, claims 1, 5 and 12-14 are examined.

Withdrawn Claim Objections

2. The previous objection to claim 1 is withdrawn in view of applicants' amendment to the claim and applicants' response at page 5 in the amendment filed August 3, 2010.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1, 5 and 12-14 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of in view of applicants' amendment to the claim and applicants' response at page 5 in the amendment filed August 3, 2010.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Serge Ilin-Schneider on August 12, 2010.

Examiner's Amendments to the Specification:

Please insert the following paragraph inserted after the title at page 1 of the specification:

Application/Control Number: 10/599,479

Art Unit: 1656

This application is a 371 of PCT/JP2005/006510, filed April 1, 2005, which claims the benefit of foreign application JAPAN 2004-110463, filed April 2, 2004.

Page 3

Examiner's Amendment to the Claims:

Cancel claims 10, 11 and 15.

Claims 1, 5, 12 and 13 have been amended as follows:

- 1. (Currently amended) An isolated peptide consisting of any one of the following amino acid sequence (A) to (D):
 - (A) the amino acid sequence shown by SEQ ID NO: 2;
 - (B) the amino acid sequence shown by position 1 to 20 of SEQ ID NO: 2;
 - (C) the amino acid sequence shown by position 5 to 24 of SEQ ID NO: 2; and
 - (D) the amino acid sequence shown by position 2 to 13 of SEQ ID NO: 2[[;]].
- 5. (Currently amended) A fusion peptide wherein comprising the peptide according to claim 1 is bound with and a marker protein, and/or a peptide tag or a combination thereof.
- 12. (Currently amended) A method for screening a cardioinhibitory factor or hypotensive factor, comprising the steps of administering an effective amount of the peptide according to claim 1 and a test substance to a non-human test animal, measuring a level of cardioinhibitory activity or hypotensive activity, and estimating the test substance as a cardioinhibitory factor in case that cardioinhibitory activity is higher when administering said peptide and said test substance than when administering the same amount of said peptide only, or estimating the test substance as a hypotensive factor in case that hypotensive activity is higher when administering said peptide and said test substance than when administering the same amount of said peptide only.
- 13. (Currently amended) A method for screening an inhibitor of cardioinhibitory activity or an inhibitor of hypotensive activity, comprising the steps of administering <u>an effective</u> amount of the peptide according to claim 1 and a test substance to a non-human test animal,

Art Unit: 1656

measuring a level of cardioinhibitory or hypotensive activity, and estimating the test substance as an inhibitor of cardioinhibitory activity in case that cardioinhibitory activity is lower when administering said peptide and said test substance than when administering the same amount of said peptide only, or estimating the test substance as an inhibitor of hypotensive activity in case that hypotensive activity is lower when administering the same amount of said peptide and said test substance than when administering said peptide only.

The following is an Examiner's Statement of Reasons for Allowance: The following reference is related to the claimed invention. Carulli *et al.* (WO 01/32875) disclose a human-derived DNA sequence (SEQ ID NO:1 or SEQ ID NO:3 of WO document) encoding a TorC polypeptide (SEQ ID NO: 2 or SEQ ID NO:4 of WO document) comprising the instant amino acid sequence of SEQ ID NO:2. However, Carulli *et al.* do not teach an isolated peptide consisting of the amino acid sequence of SEQ ID NO:2 or its fragments such as residues 1 to 20, residues 5 to 24 or residues 2 to 13 of SEQ ID NO:2. Therefore, the claims are allowable over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/599,479 Page 5

Art Unit: 1656

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

August 12, 2010